Mini MaxLock EXTREME™ System

Instructions for Use

i) CORRECT HANDLING OF IMPLANTS IS EXTREMELY IMPORTANT. Avoid contouring metallic plates when possible. If contouring is necessary, the plate should not be bent sharply, reverse bent, notched or scratched. All of these operations can produce defects in the stainless steel and internal stress concentrations, which may become the focal point for eventual failure of the device. Do not bend screws.

ii) If bending a plate through a threaded locking hole, the utilization of non-locking screws is recommended to insert through those particular holes, as the amount of deformation may inhibit threaded screws from fully seating due to deformation of the implant.

iii) If metal screws, wire bands, or other metallic devices are to be used together with the plates, all such devices should be manufactured from a metal together with the plates, the patient must be warned that bending or breakage of the device are complications that may occur as a result of the weight bearing or muscle activity. An active, debilitated or demented patient who cannot properly utilize weight support devices may be particularly at risk during postoperative rehabilitation.

iv) Removal of the Device

a) While the surgeon must make the final decision on implant removal, whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients.

b) Disposal of the Device

i) Upon removal of the implant(s), dispose of as a biohazard material.

ii) Magnetic Resonance Imaging (MRI) Safety and Compatibility

i) The Mini MaxLock EXTREME™ Plating System implants may affect image quality (image degradation or pulse sequence migration in the MR environment). The potential for success in fracture fixation is increased by the selection of the proper size, shape, and design of the implants. The patient’s anatomy will determine the size of the plate and screws to be used. The size and shape of the anatomy preclude the use of locking screws on the implants.

ii) The Mini MaxLock EXTREME™ implants are designed for smaller anatomies. For larger anatomies or higher load applications consider using the MaxLock EXTREME™ System.

iii) Patient Selection

i) When evaluating patients for orthopedic device application, the patient’s weight, occupation, activity level, and any degenerative diseases are of extreme importance to the eventual success of the procedure. These conditions must be evaluated as part of the preoperative planning. Conditions of senility, mental illness, alcoholism, and dementia must also be taken into consideration.

ii) Final treatment decision is at the discretion of the physician and patient.

iii) Device Compatibility

i) It is not recommended to use other manufacturer’s implants in any assembly or construct application in conjunction with these implants.

ii) The Mini MaxLock EXTREME™ implants are not compatible with the MaxLock EXTREME™ implants.

iv) Post-Operative Care

i) NOTE: Postoperative care is extremely important. The patient must be warned that nonunion with postoperative infection would lead to breakage of the implant requiring revision surgery to remove the device.

ii) Use of the plates provides the orthopedic surgeon a means of bone fixation and helps generally in the management of nonunions and reconstructive surgeries. These implants are intended as a guide to normal healing and are NOT intended to replace normal bone structure or bear the weight of the body in the presence of incomplete bone healing. Delayed union (healing in the presence of load bearing) may eventually cause the implant to break due to metal fatigue. All metal surgical implants are subject to repeated stress in use which can result in metal fatigue.

iii) Failure to immobilize a delayed union or nonunion of bone will result in excessive and repeated stresses which are transmitted by the body to any temporary internal fixation device to the healing of the fracture. Due to normal metal fatigue, these stresses can cause eventual bending or breakage of the device. Therefore, it is important that immobilization of the fractures site is maintained until firm bony union (confirmed by clinical and roentgenographic examination) is established.

iv) NO PARTIAL WEIGHT BEARING OR NONWEIGHT BEARING DEVICE CAN BE EXPECTED TO WITHSTAND THE UNSUPPORTED STRESSES OF FULL WEIGHT BEARING. Until firm bone union is achieved, the patient should employ adequate external support and restrict physical activities which would place stress upon the implant or allow movement at the fracture site and delay healing.

v) Detailed written instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to fusion, the patient must be warned that bending or breakage of the device are complications which may occur as a result of the weight bearing or muscle activity. An active, debilitated or demented patient who cannot properly utilize weight support devices may be particularly at risk during postoperative rehabilitation.

6) POSSIBLE ADVERSE AFFECTS

a) Loosening, bending, cracking or fracture of the plate, or loss of fixation in bone attributable to noncompliance, or uncontrollable and unstable condition of fracture.

b) Loss of anatomic position with nonunion or malunion with rotation or angulation.

i) Infection, both deep and superficial.

ii) Allergies associated with the device material.

7) CLEANING AND STORAGE

a) Store in a cool, dry place.

b) The Mini MaxLock EXTREME™ Plating System instruments are provided non-sterile and must be cleaned before use.

i) Completely disassemble instruments, as appropriate.

ii) Rinse instruments in lukewarm tap water until all visible soil is removed.

iii) Thoroughly brush the instruments using a soft-bristled brush, assuring all hard to reach areas and cannulas are accessed. A syringe or pipe cleaner may be used if applicable.

iv) Rinse instruments in lukewarm tap water until all detergent residues are removed.

v) Fully immerse instruments in a neutral pH (7.0) or mild detergent. Thoroughly brush the instruments using a soft-bristled brush, assuring all hard to reach areas and cannulas are accessed.

vi) Rinse instruments in lukewarm tap water until all detergent residues are removed.

vii) Visually inspect the instruments to ensure instruments are suitable for use and free of debris prior to sterilization.

8) STERILIZATION

a) The Mini MaxLock EXTREME™ Plating System implants and instruments are supplied non-sterile and must be sterilized before use.

i) Do not reuse implants; they are one-time use only.

ii) Do not use the device if damage is present such as nicks, gouges, or scratches.
MINI MAXLOCK EXTREME™ SYSTEM

Instruments for Use

b) Sterilize with steam sterilization. The following steam sterilization cycle is recommended based upon validation of a single Mini MaxLock Extreme™ Plating System tray with an FDA cleared sterilization wrap and an FDA cleared sterilizer using strips and suture. Flash sterilization is NOT recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79: 2006. Comprehensive guide to steam sterilization and sterility assurance in health care.

8) STERILIZATION (cont.)
   b) (cont.) facilities. Sterilization cycles beyond the prescribed parameters must be validated independently by the facility. Each facility’s process parameters should be validated for the type of sterilization equipment and product load configuration.

   (1) Recommended cycle: four minutes in a 270°F (132°C) pre-vacuum steam sterilization.
   (2) Recommended dry time: sixty minutes.
   (i) If the Mini MTP Caddy is included in the case and tray, remove the silicone mat from the utility bin and open up the ratchet on the stagbeetle forceps (MXM-062). See image below.

9) LOADER AND CONSIGNMENT SET SECTIONS
   b) All instruments and implants must be placed back in their respective trays within their appropriate sterilization case and sterilized per the sterilization instructions above prior to shipping back to the manufacturer. Any implants or instrumentation damaged due to neglect from mishandling or mispackaging will be billed to the customer.

10) RATCHETING HANDLE CARE
    b) The following guidelines are intended to provide care and handling instructions for stainless steel ratcheting drivers. These guidelines are not intended for use with electrical, pneumatic or powered surgical instruments.
    c) All instruments are shipped in a NON-STEROILE condition and MUST be cleaned, lubricated, and autoclaved prior to use.

   d) CLEANING
      i) MANUAL CLEANING
         (1) Clean instruments as quickly as possible after each use. It is important not to allow blood or debris to dry on the instruments. If cleaning must be delayed, store the ratcheting driver in a covered container with the appropriate detergent or cleaning solution to delay drying. Do not use high concentrations of chlorine bleach on stainless steel instruments or pitting will occur. Do not use abrasive pads or cleaners. This will scratch the surface of the driver and remove the protective coating. This can lead to corrosion, dirt collection, and water deposits. Sort instruments by similar metal for subsequent processing to avoid electrolytic deposition (galvanic corrosion) due to contact between dissimilar metals.
      ii) ULTRASONIC CLEANING
         (1) Ultrasonic cleaners are effective when used per the manufacturer’s instructions with specially formulated detergents. It is recommended that all visible blood and debris be removed from the instrument prior to ultrasonic cleaning. Sort instruments by similar metal for subsequent processing to avoid electrolytic deposition (galvanic corrosion) due to contact between dissimilar metals.

   e) LUBRICATION
      i) Ultrasonic cleaning effectively removes all lubricant, so it is important to re-lubricate each driver immediately after cleaning. The use of an antibacterial, lubricating rust inhibitor is highly recommended. This water-soluble lubricant should be mixed in a bath solution made with demineralized water. Instruments should be immersed in this solution for 30 seconds and allowed to drip dry. This allows for the formation of a lubricant film that will remain throughout the sterilization process and this film will continue to protect the drivers during storage. This process guards instruments from staining and corrosion during sterilization and storage.
      f) AUTOCLAVING
         i) Staining and spotting may result if residual chemicals are not completely rinsed from instruments prior to steam sterilization. It is imperative to follow the proper sterilization and drying cycles outlined in the enclosed equipment literature. Failure to follow the provided instructions may result in incomplete sterilization, excess moisture formation, and water spotting.

   g) RINSE THE DRIVER
      i) Avoid using tap water for rinsing the driver. The minerals in tap water can cause driver discoloration or staining. Use demineralized water for rinsing in order to prevent spotting. If tap water must be used for the final rinsing, dry the instruments immediately to prevent staining.
   h) MAINTAINING CORROSION RESISTANCE
      The ratcheting drivers are made of corrosion resistant specialty stainless steels. These steels form a passive oxide layer on the driver surface to protect them against corrosion. In order to maintain the quality of this protective layer, it is imperative to use and maintain the ratcheting driver properly. Failure to follow the provided instructions can lead to rust formation, which reduces the life of the instrument and the corrosion resistance.
   i) CALIBRATING TORQUE LIMITING HANDLE
      i) Calibration cycles are dependent on product handling and the frequency of use. It is recommended to return the product for torque verification or adjustment after one of the following are met:
         (1) Six months of use
         (2) 200 autoclave cycles
         (3) Approximately 3600 actuations (Clicks)
      j) IF AT ANY TIME A DEVICE SEEMS TO BE MALFUNCTIONING, REMOVE IT FROM SERVICE IMMEDIATELY AND RETURN FOR RECALIBRATION OR REPLACEMENT
   k) These guidelines are written to provide general information on the care and cleaning of surgical instruments. Attention has been paid to chemical and corrosion contacts that may inadvertently degrade, corrode, or otherwise shorten the expected life of hand held surgical instruments. These guidelines are not all-inclusive and do not outline every possible chemical contact or reaction that may occur while handling or cleaning.

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